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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,951	03/28/2006	Jian-Ping Wu	3477-112	5581
20792 7590 01/10/2007 MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627			EXAMINER KHANNA, HEMANT	
			ART UNIT 1654	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/10/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/538,951

Applicant(s)

WU ET AL.

Examiner

Hemant Khanna

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41, 43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) 31-41, 43 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/21/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of claims 1-30 that belong to Group I in the reply filed on December 01, 2006 is acknowledged. The traversal is on the ground(s) that because claims 31, 34-39 of Group II and claims 43-44 of Group III are dependent on claim I of Group I, the inventions of Groups I-III reflect a common inventive concept.

The applicant's arguments are not found persuasive. The inventions of Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The MPEP states if an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. Here the independent claim, 1 is not free of the prior art as set forth in the Restriction requirement (Page 2) filed on November 01, 2006. Further, the Applicant has not argued the invalidity of the Wu et al reference cited in the Examiner's Restriction requirement, which anticipates the special technical feature in its disclosure of a method of preparing ACE inhibitory peptide-containing hydrolysates obtained from soy meal by contacting soy meal with the enzyme Alcalase.

The restriction between Groups I, II and III is maintained.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's elected the species of Alcalase 2.4L without traverse. Applicant's species has not been found free of the prior art and is rejected under 102 (b) as set forth below.

Claims 1-30 have been examined on the merits.

Claims 31-41, and 43-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **with** traverse in the reply filed on December 01, 2006.

Claim Objections

2. Claims 9, 24 are objected to because of the following informalities: the notation of "MWCO" is unclear. For the benefit of clarity, Applicant is asked to define explicitly the notations recited in the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is directed to a method for preparing an ACE inhibitory peptide-containing hydrolysate with a "separating the meal or flour from the solvent" step. It is not clear whether the meal or flour that is being separated from the solvent is the same

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oil-free meal or flour that was first contacted with the organic solvent. It is not clear how the organic solvent is intending to limit the method and what relationship is intended between the first step of contacting the oil-free meal with the organic solvent and the second step of separating the meal from the solvent. Thus claim 1 is indefinite. Claims 2-21 depend from claim 1, and therefore are indefinite.

Claims 12, 13, and 26 recite the limitation "w/w". It is not clear how the limitation "w/w" is intended to limit the claim, in the absence of a "standard" or "reference" to which the proteolytic enzymes concentration is relative to.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 1, 3-7, 10-11, 14-16 is rejected under 35 U.S.C. 102(b) as being anticipated by Wu et al. (J. Agric. Food Chem (2001) 49: 501-506) as evidenced by Garrison et al (USPN 4,175,075).

The claims are drawn to a process for preparing angiotensin converting enzyme (ACE) inhibitory peptide-containing hydrolysates comprising contacting an oil-free seed meal or flour with a proteolytic enzyme to produce an ACE-inhibitory peptide-containing hydrolysate.

With respect to claim 1, 3-7, Wu et al disclose contacting a defatted soy meal with Alcalase to yield ACE inhibitory peptides (Abstract, Materials and Methods, page 502, Conclusion, page 505), thus meeting all the limitations of claim 1, 3-7.

To the extent that the Applicant utilized an organic solvent to contact an oil-free seed meal, before proteolysis, the method of Wu et al will inherently result in the claimed method as evidenced by Garrison et al. who teach the defatting of oleaginous seeds rich in lipids with extraction using water-alcohol systems at temperature ranges from room temperature to the boiling point of the solvent to provide high quality protein (column 8, lines 50-55; column 9, lines 1-3; claims 16-17). Hence, sufficient evidence of similarity is deemed to be present between the method of Wu et al. and the Applicant to shift the burden to the Applicant to provide evidence that the claimed method is unobviously different than that of Wu et al.

With respect to claim 10, to the extent that the Applicant obtained a powder after separating the hydrolysate from the treated seed meal, the method of Wu et al will inherently result in the claimed powder as evidenced by the disclosure of Wu et al who teach lyophilizing the fraction obtained upon ultrafiltration of the hydrolysate.

With respect to claims 11, 14-16 Wu et al disclose using a seed meal obtained from soybean. Wu et al also disclose an alkaline protease, such as Alcalase 2.4L, and the use of the enzyme for digesting the oil-free soy meal at alkaline pH which was adjusted by the addition of NaOH (Materials and Methods, see section Preparation of Soy ACE Inhibitory Peptides, page 502), thus meeting all the limitations of claims 11, 14-16.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 2, 8-9, 12-13, 17-18, 19-21, rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (J. Agric. Food Chem (2001) 49: 501-506) and Garrison et al (USPN 4,175,075) in view of Eto et al (J. Jpn. Soc. Nutr. Food Sci (1998), 51:355-359; cited by the Applicant in the IDS filed on February 21, 2006).

The claims are drawn to a process for preparing angiotensin converting enzyme (ACE) inhibitory peptide-containing hydrolysates comprising contacting an oil-free seed meal or flour with a proteolytic enzyme to produce an ACE-inhibitory peptide-containing

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hydrolysate, wherein the treated seed meal or flour is separated from the hydrolysate by ultrafiltration.

With respect to claims 1, 2, 8-9 Wu et al and Garrison et al teach as discussed above contacting an oil free soy meal with an organic solvent, and further treating the meal with Alcalase 2.4L to yield ACE-inhibitory peptide-containing hydrolysates. The hydrolysates are separated from the treated seed meal through an ultrafiltration membrane.

In view of the teachings of Wu et al and Garrison et al it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the pore size of the ultrafiltration membrane for the known and expected result of providing a means recognized in the art for recovering the ACE-inhibitory peptides with variable chain lengths having variable MW's.

With respect to claims 12-13, Wu et al teach that it is known in the art to use an enzyme-to-substrate ratio of 0.04 (4 % v/w) for the process of proteolytic digestion of the soy meal by Alcalase 2.4L. With respect to claims 17-18 and 21, Wu et al teach using NaOH to adjust the pH to 9.0 to facilitate proteolysis. With respect to claim 19, the incubation time for proteolysis was 12 h (Materials and Methods, see section Preparation of Soy ACE Inhibitory Peptides, page 502).

In view of the teachings of Wu et al it would have been obvious to one of ordinary skill in the art at the time of the invention to make adjustments of conventional working

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conditions (type enzyme (metalloendoprotease, alkaline protease, acid protease) amount enzyme, pH, incubation time) as merely a matter of judicious selection and routine optimization for providing a means for the expected result of proteolytic cleavage of proteins in soy meal, especially in the absence to the contrary.

With respect to claim 20, the references of Wu et al and Garrison et al differ from the instant claims by not reciting a hydrolysate that contains the peptide of Phe-Leu.

With respect to claims 20, Eto et al teach that it is known in the art to obtain a hydrolysate that contains the ACE-inhibitory peptide of Phe-Leu from an enzymatic hydrolysate of whey protein, wherein the whey protein is contacted with alkaline proteases.

In view of the above teachings, it would be obvious to one of ordinary skill in the art at the time of the teaching to combine the ACE-inhibitory peptides of Eto et al with the proteolytic processes of obtaining ACE-inhibitory peptides as disclosed by Wu et al and Garrison et al. It is known in the art that the peptide of Phe-Leu inhibits ACE from rabbit lung. It is also known in the art that protein meals that are a source of ACE-inhibitory peptides are ingredients for functional foods to prevent hypertension. Therefore Eto with its disclosure of Phe-Leu remedies the deficiency of Wu et al and Garrison et al, regarding Wu et al and Garrison et al's rendering obvious the identity of the ACE-inhibitory peptides.

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9. Claims 22-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (J. Agric. Food Chem (2001) 49: 501-506) as applied to claims 1, 2, 8-9, 12-13, 17, 19 above, and further in view of Tzen et al (Plant Physiol. (1993) 101:267-276).

The claims are drawn to a process for preparing angiotensin converting enzyme (ACE) inhibitory peptide-containing hydrolysates from flax free seed meal or canola seed meal comprising contacting an oil-free seed meal or flour with a proteolytic enzyme to produce an ACE-inhibitory peptide-containing hydrolysate, wherein the treated seed meal or flour is separated from the hydrolysate by ultrafiltration.

With respect to claims 22-30 Wu et al teach as discussed above contacting an oil free soy meal with Alcalase 2.4L to yield ACE-inhibitory peptide-containing hydrolysates. The hydrolysates are separated from the treated seed meal through an ultrafiltration membrane. Wu et al also disclose conventional working conditions, inclusive of enzyme concentration, for the digestion of the oil-free soy meal at alkaline pH. Further, the pH was adjusted by the addition of NaOH (Materials and Methods, see section Preparation of Soy ACE Inhibitory Peptides, page 502).

Wu et al differs from the base claim 22 by not explicitly disclosing the treatment of an oil-free flax seed meal or canola seed meal with Alcalase 2.4L for preparing ACE-inhibitory peptides.

With respect to claims 22-30, Tzen disclose that it is known in the art that oil-containing seeds such as flax, soybean also contain proteins (oleasins) among their contents (abstract; Materials and Methods, Plant Materials; Table 1, page 271).

In view of the above teachings it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the proteinaceous flax seeds with the ACE-inhibitory peptide isolation processes described by Wu et al for the known and expected result of providing a means recognized in the art to recover ACE-inhibitory peptides from seeds rich in proteins.

Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hemant Khanna whose telephone number is (571) 272-9045. The examiner can normally be reached on Monday through Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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January 03, 2006



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